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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,732	03/19/2001	David Mark Whitcombe	0380-P02328US	7974

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EXAMINER	
CHAKRABARTI, ARUN K	
ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 08/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/700,732	Whitcombe
Examiner	**Art Unit**
Arun Chakrabarti	1634

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jun 26, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 5-19, and 37* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 5-19, and 37* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 26, 2003 has been entered.

Specification

2. Claims 1, 5 and 15 have been amended. Claims 2-4 and 20 have been canceled.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (e) the invention was described in-
> (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1, 5, 6, 8-13, 15-19 , and 37 are rejected under 35 U.S.C. 102 (e) as being anticipated by Graham et al. (U.S. Patent 6,127,120) (October 3, 2000).

Graham et al teach a method for determining the presence or absence of a target nucleic acid sequence in a sample nucleic acid (Abstract), the method comprising :

(a) exposing the sample to a detection agent comprising at least two separate components, including a first agent having a metal surface associated with a first target binding species (TBS) and a second agent having a metal surface associated with a second TBS, different from the first TBS, at least one of the metal surfaces being associated with a SER(R)S-active species (SAS), each of the first and second TBS being effective to bind to the target sequence, and wherein the binding of the first and second TBS to the target sequence causes aggregation of the metal surfaces associated with the TBS, thereby causing surface enhancement of a SAS associated with one or both of the metal surfaces, the metal surfaces being ineffective to cause surface enhancement in the form in which they are present in the detection agent to which the sample is exposed, and aggregation of the metal SER(R)S surface being dependent on the presence of the target nucleic acid in the sample (Abstract, Claim 1-2, 8, 36, and Column 13, lines 37-43 and 57-65 and Column 38, lines 22-25 and Examples 1-9),

(b) observing the sample/agent mixture using SER(R)s to detect any surface enhancement (Claim 1 and Figures 3-20).

Graham et al teach a method, wherein the detection agent comprises monodisperse unaggregated colloidal metal particles associated with a TBS comprising a nucleic acid or nucleic acid analog which is complementary to all or part of the target sequence (Example 9, Column 39, lines 44-56).

Graham et al teach a method, wherein the TBS comprises peptide nucleic acid (Column 7, lines 9-11 and Column 17, lines 23-30).

Graham et al inherently teach a method, wherein there are more than one TBS per metal colloid particle (Column 29, lines 42-52);

Graham et al teach a method, wherein a surface seeking group (SSG) is used to promote chemi-sorption of the SAS and /or TBS to the metal surface (Column 20, lines 39-64 and Claim 2).

Graham et al teach a method, wherein the SSG is benzotriazole and azobenzotriazole and is modified with a dye which is SAS (Column 20, line 65 to Column 21, line 45 and Claims 18-19).

Graham et al teach a method, wherein more than one target sequence is determined using multiple detection agents having distinguishable SAS (Column 29, lines 42-52);

Graham et al teach a method, wherein

Graham et al teach a method, wherein the modified SSG is used to associate the TBS to the metal surface (Column 21, line 34 to Column 23, line 2).

Graham et al teach a method, wherein the modified SSG is conjugated to the TBS via a linker group (Column 21, line 34 to Column 23, line 2).

Graham et al inherently teach a method, wherein the target sequences share sequence identity, and wherein a common first agent is used in conjunction with specific distinguishable second agents which can discriminate between the remainder of the target sequences (Column 19, line 58 to Column 20, line 4).

Graham et al teach a method for detecting the presence of, or selecting, or identifying, or phylogenetically classifying an organism, the method comprising use of a method wherein the target nucleic acid sequence is associated with that organism (Column 32, lines 1-11).

Graham et al teach a method for diagnosing a disease, the method comprising use of a method wherein the target nucleic acid sequence is associated with that disease (Column 30, lines 17-36).

Graham et al teach a method for isolating a nucleic acid encoding a specific gene, the method comprising use of a method wherein the target sequence corresponds to a sequence associated with, or within, that gene (Column 31, lines 24-67).

Graham et al teach a method, wherein the triazole group is a benzotriazole group (Column 20, line 65 to Column 21, line 45 and Claims 18-19 and Claim 18).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 7 and 14 are rejected under 35 U.S.C. 103 (a) over Graham et al.(U.S. Patent 6,127,120) (October 3, 2000).

Graham et al teach the method of claims 1-6, 8-13, 15-20, and 37 as described above.

Graham et al do not teach the method, wherein there are more than 1-20 TBS per metal colloidal particle and wherein the SAS is present in greater than 2-100 fold excess over the TBS.

However, it is *prima facie* obvious that selection of the specific number of TBS per metal colloidal particle and specific concentration ratio of SAS over the TBS represents routine optimization with regard to production of desired binding complex and quantity as well as quality of nucleic acid analyte, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions

> of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the specific number of TBS per metal colloidal particle and specific concentration ratio of SAS over the TBS selection performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Response to Amendment

6. In response to amendment, all previous 102(b) and 103(a) rejections are hereby withdrawn. However, new 102(e) rejection and 103(a) rejection have been included.

Response to Arguments

7. Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti , Ph. D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday

to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Arun Kr. Chakrabarti

ARUN K. CHAKRABARTI
PATENT EXAMINER

Arun Chakrabarti,

Patent Examiner

July 24, 2003